



PATENT APPLICATION

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application

Inventor: Apollon Papadimitriou

Group: 1653

Serial No. 09/853,731, filed May 11, 2001
(Case Docket No. 20619 US)

Examiner: Kam, Chih Min

For: **ERYTHROPOIETIN COMPOSITION**

DECLARATION OF PASCAL SEBASTIAN BAILON
UNDER 37 CFR § 1.132

Commissioner of Patents
Washington, D.C. 20231

Sir:

I, Pascal Bailon, a citizen and resident of the United States, declare that:

1. I am the Pascal Bailon, the sole inventor named in US Patent No. 6,583,272 B1, issuing from USSN 09/604,938, filed June 27, 2000 (hereinafter the " '938 application"), and am familiar with the contents of this patent and the applications on which it is based (hereinafter "The '272 patent").

2. From 1972 to early 2003, I was employed by Hoffmann-La Roche Inc., Nutley, New Jersey, the assignee of the '272 patent, my latest position being Research Director for Biopharmaceuticals. I retired from Roche on February 1, 2003.

3. The '938 application from which the '272 patent issued claims the benefit of four earlier filed provisional applications as follows: App. No. 60/142,254, filed on July 2, 1999, App. No. 60/150,225, filed on August 23, 1999, App. No. 60/151,548, filed on August 31, 1999, and App. No. 60/166,151, filed on November 17, 1999. Internally at Roche, this patent family is designated "Case 20431."

4. Example 8, columns 15-16, of my '272 patent presents data on the stability at various temperatures of various formulations containing a pegylated erythropoietin conjugate according to the invention of the '272 patent. This example was added for the first time in the '938 application, which was filed in U S Patent Office on June 27, 2000. Neither this example nor a description of any formulation was present in the four provisional applications that were filed in 1999 and from which the '938 application claims the benefit of priority.

5. The formulations described in Example 8 of the '272 patent, including specifically in Table 3, were not prepared by me or under my direction. Instead, the information contained in Example 8 of the '272 patent was obtained from Dr. Papadimitriou, a colleague of mine who worked at Roche Diagnostics in Penzberg, Germany. On information and belief, the formulations described in Example 8 include the conjugate designated "Mono 30 K SBA" in my patent (see, e.g., Table 2).

6. Thus, the data and information contained in Example 8 of the '272 patent, including the specific formulations in Table 3, originated with Dr. Apollon Papadimitriou and are not part of my invention.

I further declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Date: 5/25/2006 Pascal Sebastian Bailon

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